

FORM PTO 1390  
(REV. 5-93)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NUMBER  
3003-00034TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

09/857682

INTERNATIONAL APPLICATION NO.  
PCT/FI99/01007INTERNATIONAL FILING DATE  
3 December 1999PRIORITY DATE CLAIMED  
8 December 1998TITLE OF INVENTION  
ARRANGEMENT IN CONNECTION WITH FEEDBACK CONTROL SYSTEMAPPLICANT(S) FOR DO/EO/US  
Anti SÄRELÄ, Mario LONCAR

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3.  This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(l).
4.  A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5.  A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a.  is transmitted herewith (required only if not transmitted by the International Bureau).
  - b.  has been transmitted by the International Bureau.
  - c.  is not required, as the application was filed in the United States Receiving Office (RO/US).
6.  A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a.  are transmitted herewith (required only if not transmitted by the International Bureau).
  - b.  have been transmitted by the International Bureau.
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
8.  A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.  An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10.  A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

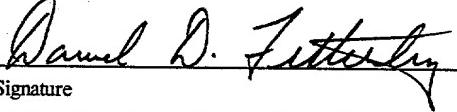
## Items 11. to 16. below concern other document(s) or information included:

11.  An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12.  An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13.  A **FIRST** preliminary amendment.  
 A **SECOND** or **SUBSEQUENT** preliminary amendment.
14.  A substitute specification.
15.  A change of power of attorney and/or address letter.
16.  Other items or information:
  - Applicant claims small entity status
  - Supplement to Transmittal Letter

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)  
**097857682**INTERNATIONAL APPLICATION NO.  
PCT/FI99/01007ATTORNEY'S DOCKET NUMBER  
3003-00034

<p>17. The following fees are submitted:</p> <p><b>Basic National Fee (37 CFR 1.492(a)(1)-(5)):</b></p> <table> <tr> <td>Search Report has been prepared by the EPO or JPO.....</td> <td>\$ 860.00</td> </tr> <tr> <td>International preliminary examination fee paid to USPTO (37 CFR 1.482)....</td> <td>\$ 690.00</td> </tr> <tr> <td>No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....</td> <td>\$ 710.00</td> </tr> <tr> <td>Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....</td> <td>\$ 1,000.00</td> </tr> <tr> <td>International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....</td> <td>\$ 100.00</td> </tr> </table> <p style="text-align: center;">ENTER APPROPRIATE BASIC FEE AMOUNT =</p>				Search Report has been prepared by the EPO or JPO.....	\$ 860.00	International preliminary examination fee paid to USPTO (37 CFR 1.482)....	\$ 690.00	No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....	\$ 710.00	Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....	\$ 1,000.00	International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....	\$ 100.00	\$1,000.00	
Search Report has been prepared by the EPO or JPO.....	\$ 860.00														
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International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....	\$ 100.00														
<p>Surcharge of \$130.00 for furnishing the National fee or oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.491(3)).</p>				+ 130.00											
Claims	Number Filed	Number Extra	Rate												
Total Claims	10 - 20 =		x \$ 18.00												
Independent Claims	1 - 3 =		x \$ 80.00												
Multiple dependent claim(s) (if applicable)				+ \$270.00											
				<b>TOTAL OF ABOVE CALCULATIONS</b>	= \$1,130.00										
<p>Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28).</p>															
				<b>SUBTOTAL</b>	= \$1,130.00										
<p>Processing fee of \$130.00 for furnishing the English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(f)).</p>															
				<b>TOTAL NATIONAL FEE</b>	= \$1,130.00										
<p>Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property +</p>															
				<b>TOTAL FEES ENCLOSED</b>	= \$1,130.00										
				Amount to be											
				Charged:											
a. <input checked="" type="checkbox"/>	A check enclosed in the amount of <u>\$ 1,130.00</u> to cover the above fees is enclosed.														
b. <input type="checkbox"/>	Please charge my Deposit Account No. <u>01.2000</u> in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.														
c. <input type="checkbox"/>	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>01.2000</u> . A duplicate copy of this sheet is enclosed.														
<p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p>															
SEND ALL CORRESPONDENCE TO:			ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 East Wisconsin Avenue, Suite 1100 Milwaukee, Wisconsin 53202												
			 Signature <span style="float: right;">Date</span> <u>Daniel D. Fetterley</u> <u>6/7/01</u>												
			<u>Daniel D. Fetterley</u> <u>20,323</u> Name Reg. No.												

07 JUN 2001

U.S. APPLICATION NO. (if known, see 37 CFR 1.52) <b>097857682</b>	INTERNATIONAL APPLICATION NO. PCT/FI99/01007	ATTORNEY'S DOCKET NUMBER 3003-00034
CERTIFICATE OF EXPRESS MAIL		
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as EXPRESS MAIL-POST OFFICE TO ADDRESSEE, in an envelope addressed to: BOX PCT, COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231 on the <u>14</u> day of June, 2001. Express Mail Label <u>EL812749929US</u> .		
Daniel D. Fetterley	20,323	
Name	Reg. No.	
	6/7/01	
Signature	Date	

SEARCHED SERIALIZED INDEXED FILED  
U.S. PATENT AND TRADEMARK OFFICE  
JUN 7 2001

PATENT  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of ) Group Art Unit:  
ANTTI SÄRELÄ ET AL. )  
Int'l. Appln. No. PCT/FI99/01007 ) Examiner:  
Int'l. Filing Date: 3 December 1999 ) ARRANGEMENT IN CONNECTION  
 ) WITH FEEDBACK CONTROL  
 ) SYSTEM

PRELIMINARY AMENDMENT

Milwaukee, Wisconsin 53202  
June 7, 2001

Box PCT Application  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

It is requested that U.S. national stage examination be carried out on the amended claims dated January 12, 2001. Prior to computing the filing fee in this application, kindly amend the above identified application, as follows. The filing fee is to be computed on the amended claims.

IN THE ABSTRACT:

A clean copy of the Abstract as published is attached. No changes to the Abstract have been made.

IN THE SPECIFICATION:

Please add the following paragraph at page 1, between the title and the first line of text as follows:

CROSS REFERENCE TO RELATED APPLICATION

The present application is the U.S. national stage application of International Application PCT/FI99/01007, filed December 3, 1999, which international application was published on June 15, 2000 as International Publication WO 00/33904 in the English

language.

## SUMMARY OF THE INVENTION

Before the paragraph beginning at line 12 of page 3 insert the following:

## BRIEF DESCRIPTION OF THE INVENTION

Before the paragraph beginning at line 3 of page 29 insert the following:

## BRIEF DESCRIPTION OF THE DRAWING

Before the paragraph beginning at line 1 of page 4 insert the following:

## DETAILED DESCRIPTION OF THE INVENTION

### IN THE CLAIMS:

Claim 8 has been amended as follows:

8. (amended) An arrangement as claimed in claim 6, characterized in that the gas sample is a fresh gas sample.

Add the following new claim.

10. (new) An arrangement as claimed in claim 7, characterized in that the gas sample is a fresh gas sample.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP



Daniel D. Fetterley  
(Reg. No. 20,323)

ADDRESS AND CERTIFICATE OF EXPRESS MAIL ATTACHED

100 East Wisconsin Avenue, Suite 1100  
Milwaukee, Wisconsin 53202  
(414) 271-7590  
Atty. Docket No. 3003-00034 (C.11915-34)

## CERTIFICATE OF EXPRESS MAIL

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<u>Daniel D. Fetterley</u>	20,323
Name	Reg. No.
<u>Daniel D. Fetterley</u>	<u>6/7/01</u>
Signature	Date

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**551 Rec'd PCT  
Attorney Docket No. 3003-00034

07 JUN 2001

**In the specification:**

Please add the following paragraph at page 1, between the title and the first line of text as follows:

**CROSS REFERENCE TO RELATED APPLICATION**

The present application is the U.S. national stage application of International Application PCT/FI99/01007, filed December 3, 1999, which international application was published on June 15, 2000 as International Publication WO 00/33904 in the English language.

**SUMMARY OF THE INVENTION**

Before the paragraph beginning at line 12 of page 3 insert the following:

**BRIEF DESCRIPTION OF THE INVENTION**

Before the paragraph beginning at line 29 of page 3 insert the following:

**BRIEF DESCRIPTION OF THE DRAWING**

Before the paragraph beginning at line 1 of page 4 insert the following:

**DETAILED DESCRIPTION OF THE INVENTION****In the claims:**

Claim 8 has been amended as follows:

8. (amended) An arrangement as claimed in claim 6 or 7, characterized in that the gas sample is a fresh gas sample.

PATENT  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	)	Group Art Unit:
ANTTI SÄRELÄ ET AL.	)	Examiner:
Int'l. Appln. No. PCT/FI99/01007	)	ARRANGEMENT IN CONNECTION
Int'l. Filing Date: 3 December 1999	)	WITH FEEDBACK CONTROL
	)	SYSTEM

U.S. Appln. No. 09/857,682

SECOND PRELIMINARY AMENDMENT

Milwaukee, Wisconsin 53202  
September 4, 2001

Box PCT  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.78(a)(2), kindly amend this application to insert reference to the prior international application and its language of publication.

The amendment is as follows.

**In the Specification:**

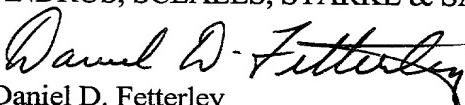
Please amend the paragraph at page 1, line 1 as follows:

**CROSS REFERENCE TO RELATED APPLICATION**

The present application is the U.S. national stage application of International Application PCT/FI99/01007, filed December 3, 1999, which international application was published on June 15, 2000 as International Publication WO 00/33904 in the English language. The International Application claims the priority of Finnish Patent Application 982653 filed December 8, 1998.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

  
Daniel D. Fetterley  
(Reg. No. 20,323)

ADDRESS AND CERTIFICATE OF EXPRESS MAIL ATTACHED

100 East Wisconsin Avenue, Suite 1100  
Milwaukee, Wisconsin 53202  
(414) 271-7590  
Atty. Docket No. 3003-00034 (C.11915-34)

## CERTIFICATE OF EXPRESS MAIL

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<u>Daniel D. Fetterley</u>	<u>20,323</u>
Name	Reg. No.
<u>Daniel D. Fetterley</u>	<u>9/4/01</u>
Signature	Date

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**Appln. No. 09/857,682**

**In the specification:**

Please amend the paragraph beginning at line 1 of page 1 as follows:

CROSS REFERENCE TO RELATED APPLICATION

The present application is the U.S. national stage application of International Application PCT/FI99/01007, filed December 3, 1999, which international application was published on June 15, 2000 as International Publication WO 00/33904 in the English language. The International Application claims the priority of Finnish Patent Application 982653, filed December 8, 1998.

### ARRANGEMENT IN CONNECTION WITH FEEDBACK CONTROL SYSTEM

The invention relates to an arrangement in connection with a feedback control system, the arrangement comprising a controllable device, a measuring device, a controlling device and a user interface by which the controlling device can be monitored by means of set values, whereby the measuring device is adapted to measure a measuring value from a measuring point, which measuring value is dependent on the operation of the controllable device, and the controlling device is adapted to monitor the controllable device on the basis of the measuring values and set values.

A basic requirement set for devices used in patient care is that they are safe and operationally reliable in the normal use of the device, in fault situations unintentionally caused by a user or in any one-fault situation of the device.

As examples of the above mentioned devices for patient care, ventilators and anaesthesia machines used in intensive care and anaesthesia can be mentioned. A patient is normally connected to a device used in patient care, e.g. to anaesthesia machine and ventilator, by means of a patient circuit. From the patient circuit there is a measuring connection to a monitor which monitors the condition of the patient. Using measuring information on the condition of the patient that the monitor provides a healthcare person supervises the condition of the patient and adjusts set values of the device used in patient care so that the measuring information corresponds to the desired value of the moment.

Characteristic of the control described above is that measuring values are only indirectly affected through the set values of the device used in patient care, and also that the control has a long-term effect. Some of these indirect pairs of measuring values and set values are listed in the table below by way of example.

Measuring value	Operative set value
Anaesthetic gas concentration of respiration	Anaesthetic concentration of anaesthesia machine vaporizer and gas flow of gas mixer
Oxygen concentration of respiration	Oxygen flow of gas mixer
Nitrous oxide concentration of respiration	Nitrous oxide flow of gas mixer
Carbon dioxide concentration of respiration	Minute ventilation of ventilator
Patient airway pressure	Respiration volume of ventilator

Dependence between measuring parameters and the operative set value may include several control systems within each other. For example, blood pressure can be regulated by means of anaesthetic concentration of exhalation, whereby the anaesthetic concentration in turn is regulated by means of the anaesthetic concentration of anaesthetic vaporizer of the gas mixer according to the table above.

Due to indirectness and a long time constant, the exact adjustment of measuring values is slow and difficult, which leads to variation in patient values, and this in turn may have harmful effects on the end result of nursing.

To improve the situation, a variety of solutions have been suggested for automatizing a control loop. In such a system, a controller, instead of a person taking care of the patient, closes the control system between the measuring value and the set value of the device for patient care, which controller is capable of considering prevailing indirectnesses and the effect of the control time constant and thus of automatically optimising the set value. With such a system in use, a healthcare person only needs to set a desired value into the control system. For example US Patent 5 094 235 describes a similar automatized control system as above. In addition, several examples can be found in literature which describe the superiority of an automatized control system over a healthcare person in achieving and maintaining patient values. As an example, the publication Westenskow D., Closed loop control of blood pressure, ventilation and anesthesia delivery, Int J. Clin. Monitoring and Computing 4: 69-74, 1987 can be mentioned. A summary of such potential control systems is given in the publication A model for technology assessment as applied to closed loop infusion systems, Critical Care Medicine, Vol 23, No 10, 1995.

In spite of the above factors, feedback control systems have not become more common in nursing environments. One reason why the solutions, practicable as such, have remained at exploratory and experimental stages are the above mentioned safety and reliability requirements set for the equipment. An automatic feedback complicates the system considerably and brings new possibilities of fault situations, the existence of which should be taken into account when implementing the equipment. Safety issues have been taken into account e.g. in the control system of an infusion system affecting muscle relaxation, David G. Mason et al., Development of a portable

closed-loop atracurium infusion system: systems methodology and safety issues, Int. J. Clin. Monitoring and Computing 13: 243-252, 1997. This research introduces methods for equipment planning, which substantially improve the safety of the system.

5 As stated above, a safety risk is substantially present in the feed-back control system, as only devices for patient care are planned to cope with one-fault situations in operational environments. Basically, the user is often responsible for the reliability of a measurement result given by the monitor. Measuring equipment and the above experimental control systems have not  
10 been planned such that one-fault situations would not create a danger for a patient.

The object of the invention is to provide an arrangement by which the prior art disadvantages can be eliminated. This is achieved by the arrangement according to the invention, characterized in that the arrangement comprises means adapted to feed a reference signal to the measuring device periodically and that the controlling device is adapted to compare the measuring value obtained on the basis of the reference signal with the real reference value of the reference signal and adapted to take a safety measure when the measuring value and the reference value differ substantially from each other.

Above all the invention provides the advantage that measuring devices on the market do not have to be redesigned for one-fault situations. A fault is recognised by an external controller which automatically checks the operation of the measuring device as a whole by means of reference measurement. The automatic checking can usually be performed by employing a  
25 very simple technique. An independent reference source is also easily available in the system. Due to simplicity, the actual controller can be straightforwardly planned against one-fault situations, and the end result is advantageous in all respects.

In the following the invention will be described in greater detail by  
30 means of examples illustrated in the attached drawing, in which

Figure 1 shows a schematic view of an operational environment of equipment used in patient care,

Figure 2 shows a diagram of an example of an automatic control arrangement of a gas dispenser in an anaesthesia machine, and

35 Figure 3 shows a diagram of an embodiment of the arrangement according to the invention.

Figure 1 shows a schematic view of an operational environment of equipment used in patient care. A patient 1 is connected to a device used in patient care, which, in the example of Figure 1, is a combination of a gas mixer and ventilator 2. The patient is connected by means of a patient circuit 3. From 5 the patient circuit 3 there is a measuring connection 4 to a monitor 5 which monitors the condition of the patient. A healthcare person 6 supervises the condition of the patient on the basis of the measuring information on the condition of the patient provided by the monitor 5 and, when necessary, adjusts set values of the device used in patient care such that the measuring information corresponds to the desired value of the moment, as explained above.

Figure 2 for its part shows a control system, in which a gas dispenser of an anaesthesia machine is automatically controlled on the basis of a signal given by breathing gas measurement of the monitor. If, as a result of a fault situation, a gas monitor 7 measures a lower anaesthetic gas concentration 8 than it in fact is or does not measure it at all, a controller 9 sets a gas dispenser 10 to produce a higher anaesthetic gas concentration than it actually should be according to a user 12. This leads to an overdose of the anaesthetic and thus to a dangerous situation. Gas concentrations shown in Figure 2 are only exemplificational values. In Figure 2, a patient circuit is indicated by the reference number 13, a CO<sub>2</sub> absorber by the reference number 14 and a ventilator by the reference number 10a. As in the example of Figure 1, a patient is marked with the a reference number 1.

In principle, the system of Figure 2 operates in the following way. While a patient is under treatment, the gas dispenser 10 feeds a desired gas mixture to the patient and the gas monitor 7 measures the anaesthetic gas concentration and informs the controller 9 of it. The controller 9 adjusts the setting of the anaesthetic gas concentration in order to achieve the desired end result. The user 12 has naturally set a desired anaesthetic gas concentration of the patient's exhalation to the controller 9.

The control system of Figure 2 has the disadvantages described above, which have been eliminated by the invention.

Figure 3 shows schematically a preferred embodiment of an arrangement according to the invention. Figure 3 uses the same reference numbers as Figure 2 in the corresponding parts, as in the embodiment of Figure 3 35 the invention is applied to the control system of Figure 2.

In the solution of Figure 3, a mechanism 15a, 15b, 15c is connected

to a separate controller 9, the mechanism changing at suitable intervals sample gas collected by a gas monitor 7 by alternating between the actual gas to be measured, i.e. a breathing gas sample 8, and reference gas, e.g. a fresh gas sample 16. A controller 9 can be a separate controller as in the example 5 of the figure, but it can also be integrated to the monitor or the controllable device. A reference signal is thus given periodically to the gas monitor, the reference signal comprising a fresh gas sample in the example of the figure. Regardless of the gas monitor, the gas dispenser 10 is perfectly aware of the real 10 anaesthetic concentration of the reference gas. The real concentration value 17 of the reference gas given by the gas dispenser and the measuring value 18 of the monitor obtained from the reference gas sample, or reference signal, that is fed to it, are fed by means of e.g. a serial port to the controller that compares these two values with each other. If the accuracy of the values is not approximately the same, the controller detects the fault situation of the 15 measuring device 7 and takes a suitable safety measure, e.g. stops setting the gas dispenser 10 concentration 19 and disconnects the control of the controllable device. Opening a safety valve or giving a suitable alarm signal, for example, can also be regarded as safety measures. An alarm signal may be based on e.g. sound or light effect, or both.

20 A reference signal need not necessarily be a fresh gas sample as in the example of the figure, but also a sample taken from e.g. indoor air or some other gas having a known concentration can be the gas sample forming the reference signal. A reference signal need not necessarily be a gas sample either, but electric measurement can also use a simulated electric signal, for 25 example, as a reference signal. On pressure side, e.g. circuit pressure measured by a ventilator can act as a reference.

A controller and a change-over mechanism of a gas sample must also be planned to take one-fault situations into account. Otherwise a valve malfunction, for example, could lead into a situation in which, when the collecting point of a sample is changed, this does not actually happen, and the 30 real fault situation remains unobserved. In Figure 3, the malfunction of the actual selector valve 15a is observed by backup valves 15b, 15c. A CPU 20 controls these valves in the corresponding manner as the selector valve 15a. If the selector valve is stuck in either position, the backup valve closes the sample line. Then the gas monitor does not measure any concentration at all and the measuring results do not accord. In addition, a monitor pump creates low 35

pressure to the sample line, which can also be detected from the monitor alarm. Correspondingly, potential leaks can always be discovered from unmatching measuring results. A controller can also be constructed in a way that one-fault situations e.g. in the CPU or controller electronics are detected. If 5 desired, the CPU of the gas dispenser can also be utilized, which CPU supervises the controller operation by means of a serial interface.

The above embodiment is not intended to restrict the invention in any way, but the invention may be modified completely freely within the scope of the claims. Therefore, it is obvious that the arrangement of the invention or 10 its details do not necessarily have to be exactly the same as shown in the figures, but other solutions are possible, too. The invention is by no means restricted to the measurement of anaesthetics only. A similar arrangement can be used e.g. in the checking of carbon dioxide, blood pressure and many other physiological measurements. The main thing is that a known independent reference has to be arranged for the measurement, which reference can be fed 15 automatically to a measuring device belonging to a closed control system.

DRAFT - 2000-07-20

12 -01- 2001

CLAIMS

1. An arrangement in connection with a feedback control system connected to an anaesthesia machine, the arrangement comprising a controllable device (10), a measuring device (7), a controlling device (9) and a user interface by which the controlling device (9) can be monitored by means of set values, whereby the measuring device (7) is adapted to measure a measuring value (8) from a measuring point, which measuring value is dependent on the operation of the controllable device and the controlling device (9) is adapted to monitor the controllable device (10) on the basis of the measuring values and set values, **characterized** in that the arrangement comprises means (15a, 15b, 15c) adapted to feed a reference signal (16) to the measuring device (7) periodically and that the controlling device (9) is adapted to compare the measuring value (18) obtained from the measuring device (7) on the basis of the reference signal with the real and known reference value (17) of the reference signal and adapted to take a safety measure when the measuring value (18) obtained on the basis of the reference signal and the real and known reference value (17) differ substantially from each other.

2. An arrangement as claimed in claim 1, **characterized** in that a safety measure is the disconnection of the control of a controllable device.

3. An arrangement as claimed in claim 1, **characterized** in that a safety measure is the opening of a safety valve.

4. An arrangement as claimed in claim 1, **characterized** in that a safety measure is the giving of an alarm signal.

5. An arrangement as claimed in claim 1, **characterized** in that the controllable device (10) comprises a gas mixer and/or ventilator used in patient care, and that the measuring device (7) is a gas monitor and that the controlling device (9) is a separate controller.

6. An arrangement as claimed in claim 1, **characterized** in that the reference signal (16) is a gas sample.

7. An arrangement as claimed in claim 6, **characterized** in that means for feeding the reference signal (16) comprise a selector valve (15a) adapted to periodically change a breathing gas sample (8) flowing to the gas monitor for a gas sample used as a reference signal (16).

8. An arrangement as claimed in claim 6 or 7, **characterized**

in that the gas sample is a fresh gas sample.

9. An arrangement as claimed in claim 7, characterized in that backup valves (15b, 15c) are adapted to supervise the operation of the selector valve (15a).

## ABSTRACT OF THE DISCLOSURE

The invention relates to an arrangement in connection with a feedback control system, the arrangement comprising a controllable device (10), a measuring device (7), a controlling device (9) and a user interface by which the controlling device (9) can be monitored by means of set values. The measuring device (7) is adapted to measure a measuring value (8) from a measuring point, which measuring value is dependent on the operation of the controllable device and the controlling device (9) is adapted to monitor the controllable device (10) on the basis of the measuring value and set values. To improve safety, the arrangement comprises means (15a, 15b, 15c) adapted to feed a reference signal (16) to the measuring device (7) periodically. The controlling device (9) is adapted to compare a measuring value (18) obtained from the reference signal with the real reference value (17) of the reference signal and adapted to take a safety measure when the measuring value (18) and the real reference value (17) differ substantially from each other.

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Fig. 1

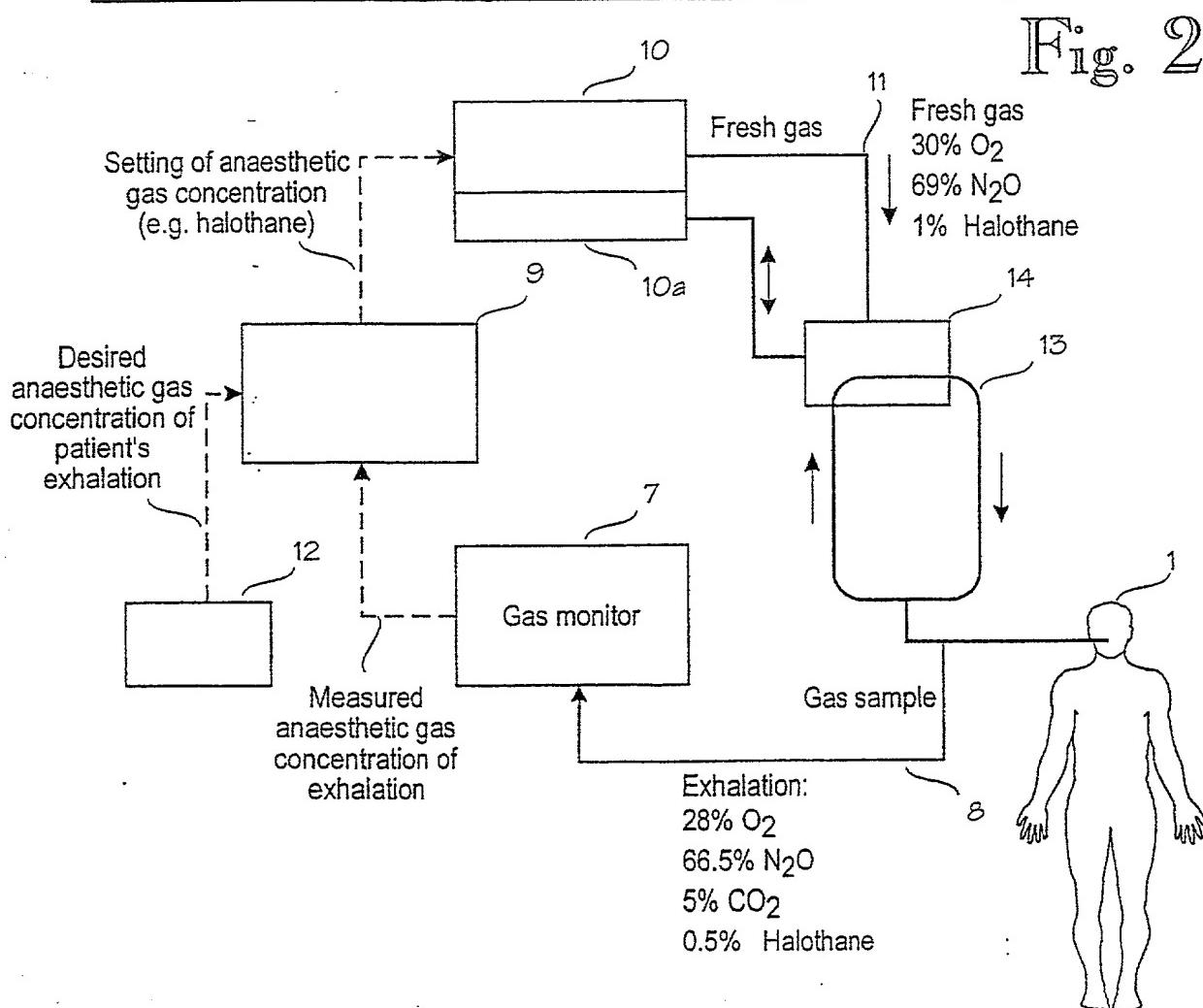
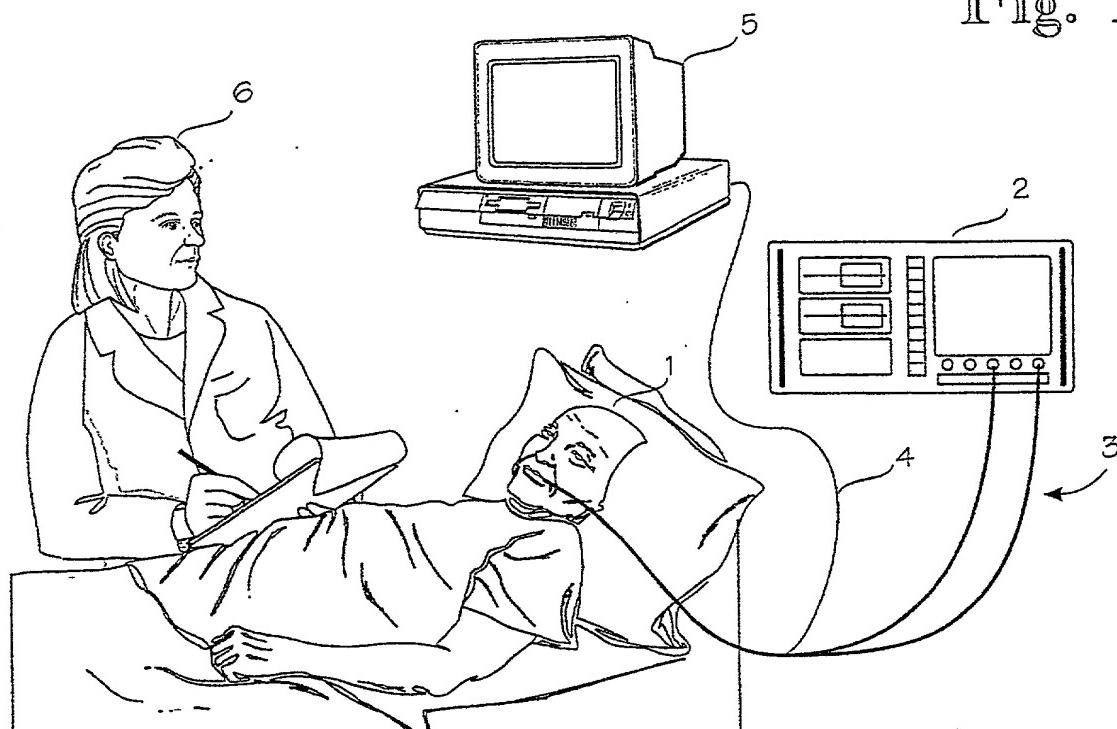
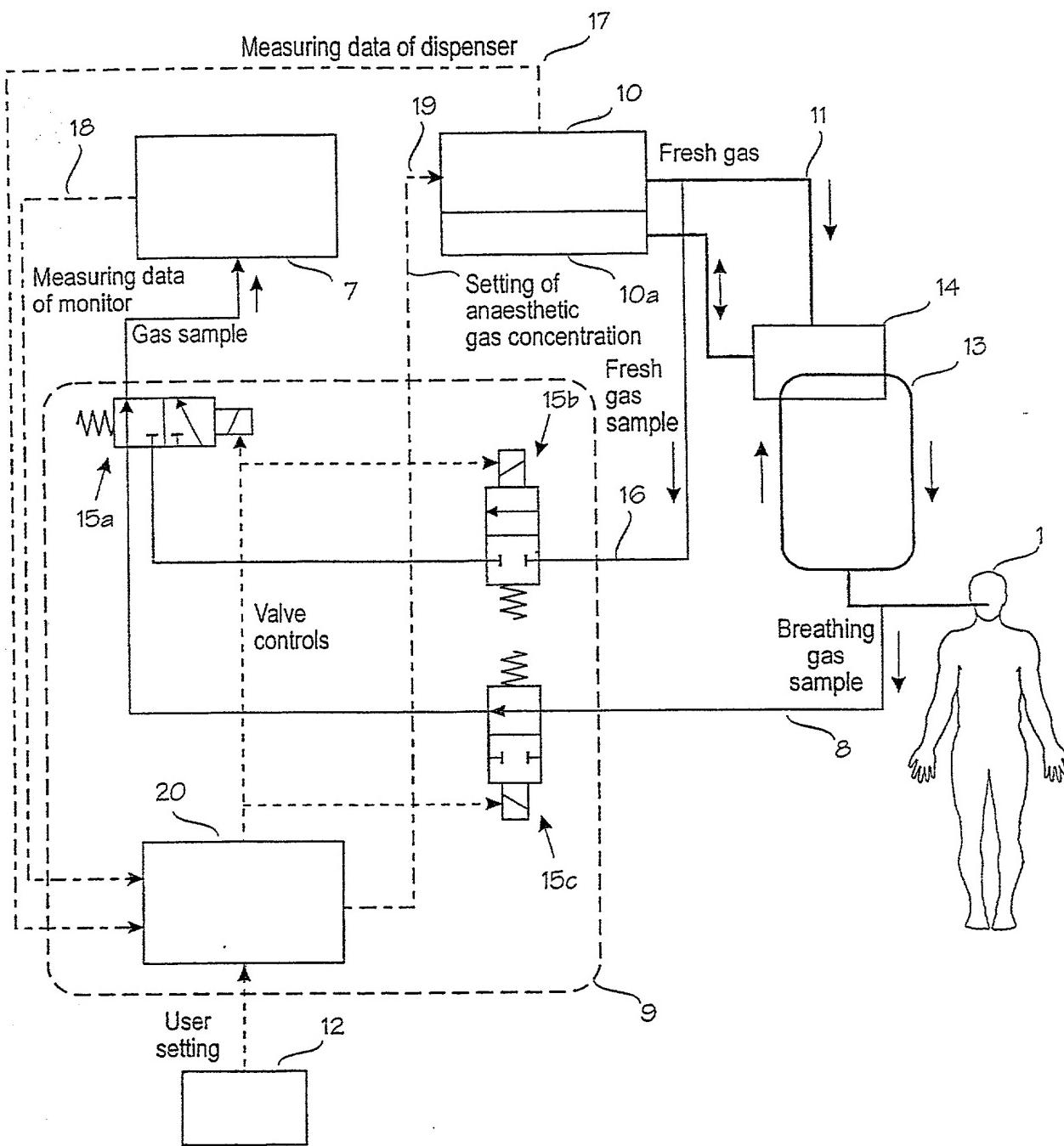


Fig. 3



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Approved for use through 9/30/00

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PTO/SB/01 (8/96)	<b>DECLARATION</b>		Attorney Docket Number <b>3003-00034</b>	
	OR		First Named Inventor <b>Antti SARELA</b>	
	Declaration <input type="checkbox"/> Submitted with Initial Filing	Declaration <input checked="" type="checkbox"/> Submitted after Initial Filing	COMPLETE IF KNOWN	
			Application Number <b>09/857,682</b>	
			Filing Date <b>7 June 2001</b>	
			Group Art Unit	
			Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Arrangement in connection with feedback control system

(Title of the Invention)

the specification of which  
 is attached hereto

OR

X was filed on (MM/DD/YYYY)  as United States Application Number or PCT

International Number (if applicable)  PCT/FI99/01007 and was amended on (MM/DD/YYYY)  12 January 2001

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Copy Attached? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
982653	Finland	8 December 1998	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> X <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority sheet attached hereto:

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.
		<input type="checkbox"/>

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### DECLARATION

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365© of any PCT international application designated the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States of PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112 I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto.

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Name	Registration Number	Name	Registration Number
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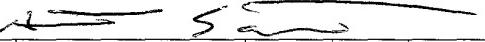
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**Name of Sole or First Inventor:**  A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
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Antti

SÄRELÄ

Inventor's Signature		Date	2.7.2001
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Mario

LONCAR

Inventor's Signature		Date	2.8.2001
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